K091547

510(k) Summary

(as required by 21 CFR 807.92)

JAN 15 2010

Submitter: **Nova Biomedical Corporation**
200 Prospect Street
Waltham, MA 02454 U.S.A.

Correspondent: Paul W. MacDonald
Chief Quality Assurance and Regulatory Affairs Officer

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Device Name:

Nova Max Plus Blood Glucose and β-Ketone Monitoring System

Common Name:

Whole Blood Glucose and Ketone Test System

Classification:

Division of Clinical Laboratory Devices
Clinical Chemistry and Toxicology Panel
Glucose Test System
Class II per 21 CFR 862.1345
Ketone Test System
Class I per 21 CFR 862.1435

Product Codes:

NBW, CGA, JIN, JJX

Predicate Devices:

Nova Max Blood Glucose Monitor, K070255,
Precision Xtra Advanced Diabetes Management System, k040814

Description of the Device:

The Nova Max Plus Blood Glucose and β- Ketone Monitoring System consists of:

1. Nova Max Plus Blood Glucose and β-Ketone Monitor
2. Nova Max Glucose Test Strips
3. Nova Max Glucose Control Solutions (Normal, Low and High)
4. Nova Max Plus β-Ketone Test Strips
5. Nova Max Plus β-Ketone Control Solutions (Levels 1,2 and 3)

Intended Use/Indications for Use:

The Nova Max Plus Blood Glucose and β-Ketone Monitoring System Monitor is intended to be used for the quantitative measurement of glucose or β-hydroxybutyrate (β-ketone) in fresh capillary whole blood. It is intended for use by people with diabetes mellitus in the home and by healthcare professionals in clinical settings as an aid to

monitor the effectiveness of diabetes control. It is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. The Nova Max Blood Glucose and β-Ketone Monitor is specifically indicated for the quantitative measurement of glucose in fresh capillary whole blood samples obtained from the fingertip, forearm and palm or β-hydroxybutyrate (β-ketone) in fresh capillary whole blood obtained from the fingertip only.

Nova Max Glucose Test Strips are intended for use only with the Nova Max Blood Glucose Monitor and the Nova Max Plus Blood Glucose and β-Ketone Monitor. The Glucose Monitor is calibrated to provide plasma equivalent results to laboratory methods. Nova Max Blood Glucose Test Strips are for testing outside the body (in vitro diagnostic use only).

The Nova Max Plus Ketone Test Strips are intended for use only on the Nova Max Plus Blood Glucose and β-Ketone Monitor.

Nova Max Glucose Control Solutions are intended for use with the Nova Max Blood Glucose Monitor, the Nova Max Plus Blood Glucose and β-Ketone Monitor and Nova Max Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results. There are three levels of controls, (Normal, Low, High).

Nova Max Plus Ketone Control Solutions are intended for use with Nova Max Plus Blood Glucose and β-Ketone Monitor and Nova Max β-Ketone Test Strips as a quality control check to verify the accuracy of blood ketone test results. There are three levels of controls, (Levels 1,2 and 3).

Summary of Technological Characteristics:

The Nova Max Plus Blood Glucose and Ketone Monitoring System has the same fundamental scientific technology and the same intended use as the current on-market Nova Max Blood Glucose Monitor (K070255) for glucose. The Nova Max Plus Blood Glucose and Ketone Monitoring System is substantially equivalent to the predicate device,.Precision Xtra Advanced Diabetes Management System, K040814, for ketone measurements.

The Nova Max Plus Blood Glucose and β- Ketone Monitoring System measures glucose electrochemically utilizing the glucose oxidase test system described in K070255 (Nova Max Glucose Monitor System. In the same manner, the magnitude of the current is proportional to the amount of glucose or, β-hydroxybutyrate *(β-* ketone) present in the sample, providing a quantitative measure of glucose or β-ketone in whole blood and control solutions.

Comparison to Predicate Devices:

The modified Nova Max Plus Blood Glucose and β-Ketone Monitoring System uses the same fundamental scientific technology and has the same intended use as the predicate Nova Max Blood Glucose Monitor (K070255) and the Precision Xtra Advanced Diabetes Management System (K040814).

Performance Studies:

The performance of the Nova Max Plus Blood Glucose and β-Ketone Monitoring System was studied in the laboratory and in clinical settings by healthcare professionals and lay users. The studies demonstrated that lay users can obtain blood glucose and blood β-Ketone results that are substantially equivalent to the current methods for blood glucose and blood β-ketone measurements.

Conclusion:

Results of laboratory and clinical testing demonstrate that the performance of the Nova Max Plus Blood Glucose and β-Ketone Monitoring System, has the same intended uses, with similar technological characteristics and can produce results that are substantially equivalent to results obtained on the predicate devices. The system performs as intended and raises no new safety or effectiveness issues. .

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JAN 15 2010

Nova BioMedical Corporation
c/o Mr. Paul W. MacDonald
Chief Quality Assurance
& Regulatory Affairs Officer
200 Prospect Street
Waltham, MA 02454-9141

Re: k091547
Trade Name: Nova Max Plus Blood Glucose and β-Ketone Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: NBW, CGA, JIN, JJX
Dated: November 17, 2009
Received: November 18, 2009

Dear Mr. MacDonald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K091547

Device Name: **Nova Max Plus Blood Glucose and β-Ketone Monitor System**

Indications for Use:

The Nova Max Plus Blood Glucose and β-Ketone Monitoring System Monitor is intended to be used for the quantitative measurement of glucose or β-hydroxybutyrate (β-ketone) in fresh capillary whole blood. It is intended for use by people with diabetes mellitus in the home and by healthcare professionals in clinical settings as an aid to monitor the effectiveness of diabetes control. It is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. The Nova Max Blood Glucose and β-Ketone Monitor is specifically indicated for the quantitative measurement of glucose in fresh capillary whole blood samples obtained from the fingertip, forearm and palm or β-hydroxybutyrate (β-ketone) in fresh capillary whole blood obtained from the fingertip only.

Nova Max Glucose Test Strips are intended for use only with the Nova Max Blood Glucose Monitor and the Nova Max Plus Blood Glucose and β-Ketone Monitor. The Glucose Monitor is calibrated to provide plasma equivalent glucose results to laboratory methods. Nova Max Blood Glucose Test Strips are for testing outside the body (in vitro diagnostic use only).

The Nova Max Plus Ketone Test Strips are intended for use only on the Nova Max Plus Blood Glucose and β-Ketone Monitor.

Nova Max Glucose Control Solutions are intended for use with the Nova Max Blood Glucose Monitor and the Nova Max Plus Blood Glucose and β-Ketone Monitor and Nova Max Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results. There are three levels of glucose controls, (Normal, Low, High).

Nova Max Plus Ketone Control Solutions are intended for use with the Nova Max Plus Blood Glucose and β-Ketone Monitor and the Nova Max Plus Ketone Test Strips as a quality control check to verify the accuracy of blood ketone test results. There are three levels of ketone controls, (Levels 1,2 and 3).

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use X (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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